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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 93F–0132]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in clay-type fillers for paper and paperboard intended for use in contact with aqueous and fatty food. This action is in response to a petition filed by Lonza, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–4183094.

SUPPLEMENTARY INFORMATION:

NFR1

I. Background

In a notice published in the **Federal Register** May 17, 1993 (58 FR 28882), FDA announced that a food additive petition (FAP 3B4367) had been filed by Lonza, Inc., c/o Delta Analytical Corp., 1414 Fenwick Lane, Silver Spring, MD 20910. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105), § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in adhesives, resinous and polymeric coatings and clay-type fillers for paper and paperboard in food-contact articles. Lonza, Inc., is currently represented by Lewis and Harrison, 122 C St. NW., suite 740, Washington, DC 20001. (Formerly represented by Delta Analytical Corp. whose current address is 7910 Woodmont Ave., Bethesda, MD 20814).

When the petition was filed on May 17, 1993, the petitioner proposed to amend the food additive regulations in §§ 175.105, 175.300, and 176.170. Subsequent to the filing of the petition, the petitioner amended the petition to limit the use of the additive to the manufacture of paper and paperboard under § 176.170.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive, a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in clay-type fillers for paper and paperboard intended to contact aqueous and fatty food is safe; (2) the additive will achieve its intended technical effect; and therefore, (3) the regulation in § 176.170(a)(5) should be amended as set forth below.

FDA's review of the petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a

carcinogen by the inhalation route, but the Committee concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two-year drinking-water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, ''* * * that data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical detail in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

A mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin intended as a preservative in clay-type fillers for paper and paperboard intended in contact with aqueous and fatty foods is regulated under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) as a food additive and not as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). However, this intended use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market food-contact articles containing a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

II. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the* **Federal Register**]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be

submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Soffritti, M., C. Maltoni, F. Maffei, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, vol. 5, No. 5, pp. 699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking-Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of Conferences concerning ''Formaldehyde,'' Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding an entry under the headings ''List of Substances'' and ''Limitations'' to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

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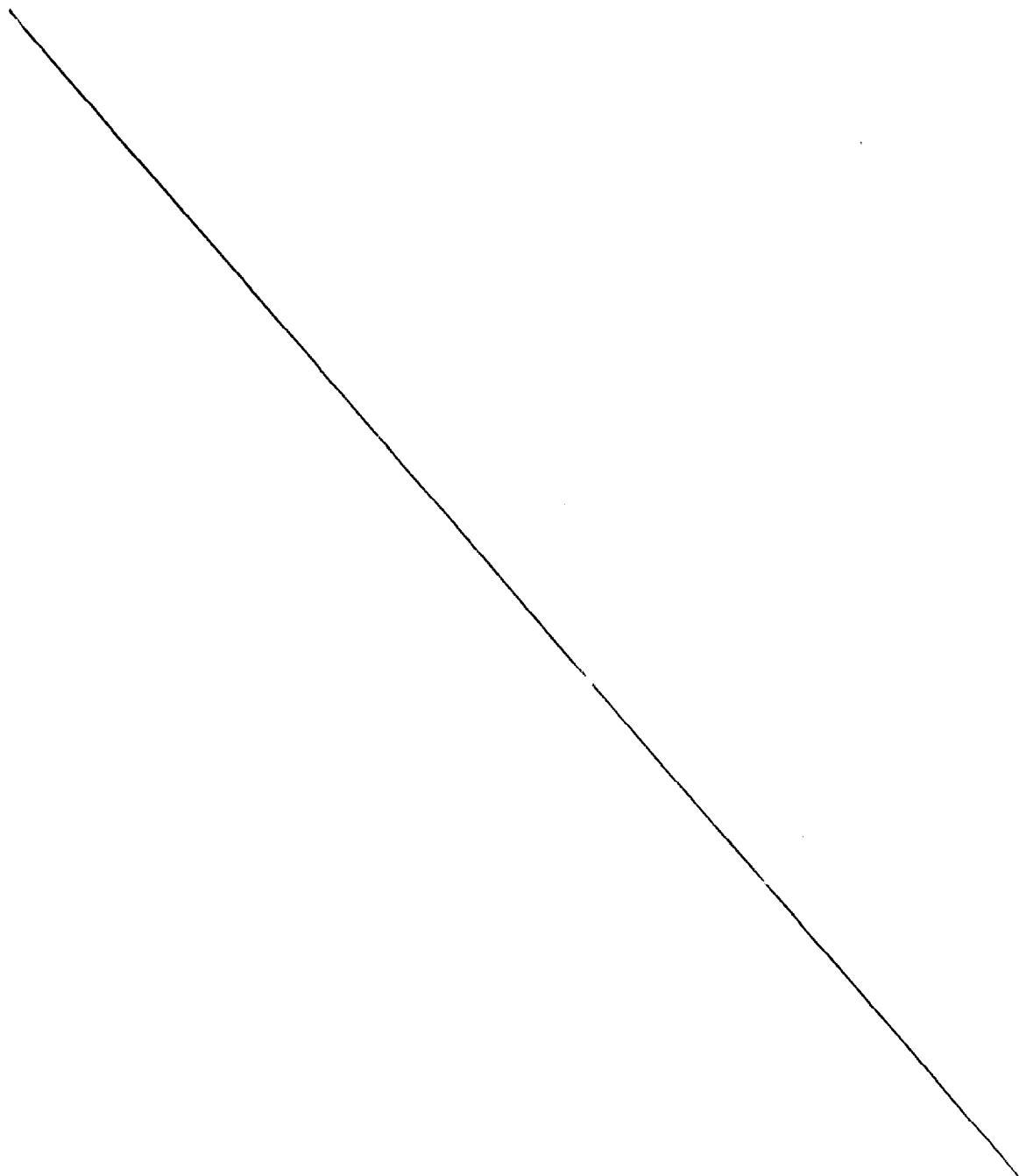
(a) * * *

(5) * * *



List of Substances	Limitations
* * * *	* * *
Hydroxymethyl-5,5-dimethylhydantoin (CAS Reg. No. 27636–82–4), mixture with 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (CAS Reg. No. 6440–58–0).	For use only as a preservative in clay-type fillers at a level not to exceed a combined total of 1,200 milligrams/kilograms hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin in the filler.
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Dated: 3 20-00
March 20, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windsor

Margaret M. Dotzel
Acting Associate Commissioner for Polciy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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